Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in August 2002.

New Approvals

ANADA Number: 200-327

Pioneer Product:	131-392
Trade Name:	Privermectin™ Drench for Sheep
Ingredients:	Ivermectin
Sponsor:	First Priority, Inc.
Approval Date:	May 15, 2002
Status:	Over-the-counter
Route:	Oral
Species:	Sheep
Drug Form:	Liquid (solution)
Concentration:	0.08%
Indications:	For the treatment and control of : **Gastrointestinal roundworms; adults and fourth-stage larva:** *Haemonchus contortus, H. placei* (adults), *Ostertagia circumcincta, Trichostrongylus axei, T. colubriformis*, *Cooperia curtitei, C. oncophora* (adults only), *Nematodirus spathiger*, N. *battus, Strongyloides papillosus* (adults only), *Oesophagostomum columbianum, O. venulosum* (adults only), *Trichuris ovis* (adults only), *Chabertia ovina* (adults only) **Lungworms:** *Dictyocaulus filaria* (adults and fourth-stage larvae) **Nasal bots:** *Oestrus ovis* (all larval stages)
Tolerance:	21CFR 556.344 Ivermectin: A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in liver (target tissue) of sheep at 30 parts per billion.
Withdrawal:	11 days

21CFR 520.1194 and *520.1195*

Supplemental Approvals

ANADA Number: 200-026

This supplemental application provides for a zero day preslaughter withdrawal in swine.

Trade Name:	Pennox™ 343
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	PennField Oil Company
Approval Date:	April 10, 2002
Status:	Over-the-counter
Route:	Oral, via drinking water
Species:	Swine
Drug Form:	Powder (soluble)
Concentration:	102.4 grams per 4.78 ounce packet or 512 grams per 23.9 ounce packet
Indications:	For the control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida;* and for breeding swine, leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona.*
Tolerance:	***21CFR 556.500*** Oxytetracycline: Tolerances are established for the sum of residues in tissues of swine as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	Swine: zero days

21CFR 520.1660d

NADA Number: 008-804

This supplemental application provides for a zero day preslaughter withdrawal in swine.

Trade Name:	TM-50®, TM-50®D, TM-100®, TM-100®D Type A Medicated Articles
Ingredients:	Oxytetracycline (from oxytetracycline quaternary salt) equivalent to oxytetracycline hydrochloride
Sponsor:	Phibro Animal Health
Approval Date:	April 29, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species	Swine
Drug Form:	Type A Medicated Article to make Type C medicated feeds.
Concentration:	50 or 100 grams per pound activity of Type A Medicated Article.
Indications:	For increased rate of weight gain and improved feed efficiency; the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida;* and for breeding swine, leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona.*
Tolerance:	***21CFR 556.500*** Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of swine, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	Swine: zero days

21CFR 558.450

NADA Number: 095-143

This supplemental application provides for a zero day preslaughter withdrawal in swine.

Trade Name:	OXTC® 50, OXTC® 100, OXTC® 200 Type A Medicated Articles
Ingredients:	Oxytetracycline
Sponsor:	Phibro Animal Health
Approval Date:	April 29, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Article to make Type C medicated feeds.
Concentration:	50, 100, or 200 grams per pound activity of Type A Medicated Article.
Indications:	For increased rate of weight gain and improved feed efficiency; the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, bacterial pneumonia caused by *Pasteurella multocida;* and for breeding swine, leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona.*
Tolerance:	***21CFR 556.500*** Oxytetracycline: Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of swine, as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal:	Swine: zero days

21CFR 558.450

NADA Number: 135-940

This supplemental application provides for an expanded dose range for the treatment of certain bacterial infections.

Trade Name:	Antirobe Aquadrops® Liquid
Ingredients:	Clindamycin hydrochloride
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	May 13, 2002
Status:	Prescription only
Route:	Oral
Species:	Dogs and cats
Drug Form:	Liquid (solution)
Concentration:	25 milligrams per milliliter
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below: **Dogs:** Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). Deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. Dental infections due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens.* **Cats:** Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). Deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. Dental infections due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

21CFR 520.447

NADA Number: 120-161

This supplemental application provides for an expanded dose range and for use of a 300-milligram strength capsule.

Trade Name:	Antirobe® Capsules
Ingredients:	Clindamycin hydrochloride
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	May 13, 2002
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Capsules
Concentration:	25, 75, 150 and 300 milligrams per capsule
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below: Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). Deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. Dental infections due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens.*

21CFR 520.446

Change of Sponsor

NADA Number: 141-200

From: DEC International, Inc.

To: Pharmacia & Upjohn Co.
7000 Portage Rd.
Kalamazoo, MI 49001-0199
Drug labeler code: 000009

ANADA Number: 200-168

From: Equi Aid Products, Inc.

To: Farnam Companies, Inc.
301 West Osborn
Phoenix, AZ 85013-3928
Drug labeler code: 017135

Change of Sponsor Name

From: Blue Ridge Pharmaceuticals, Inc.

To: IDEXX Pharmaceuticals, Inc.
4249-105 Piedmont Pkwy.
Greensboro, NC 27410
Drug labeler code: 065274

Change of Sponsor Address

From: Endo Pharmaceuticals, Inc.
223 Wilmington West Chester Pike
Chadds Ford, PA 19317
Drug Labeler Code: 060951

To: 100 Painters Dr.
Chadds Ford, PA 19317